



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2014-N-0002]

Oral Dosage Form New Animal Drugs; Withdrawal of Approval of New Animal Drug

Application; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of an abbreviated new animal drug application (ANADA) for an oxytetracycline soluble powder used to make medicated drinking water for livestock and poultry. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9075, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5 has requested that FDA withdraw approval of ANADA 200-305 for Oxytetracycline Hydrochloride Soluble Powder because the product is no longer manufactured or marketed. Note this ANADA was identified as being affected by guidance for industry (GFI) #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on

Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209", December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of ANADA 200-305, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: December 9, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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